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Ms. Seema Verma
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: Medicare Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals: Proposed Rule for 2020

Dear Administrator Verma:

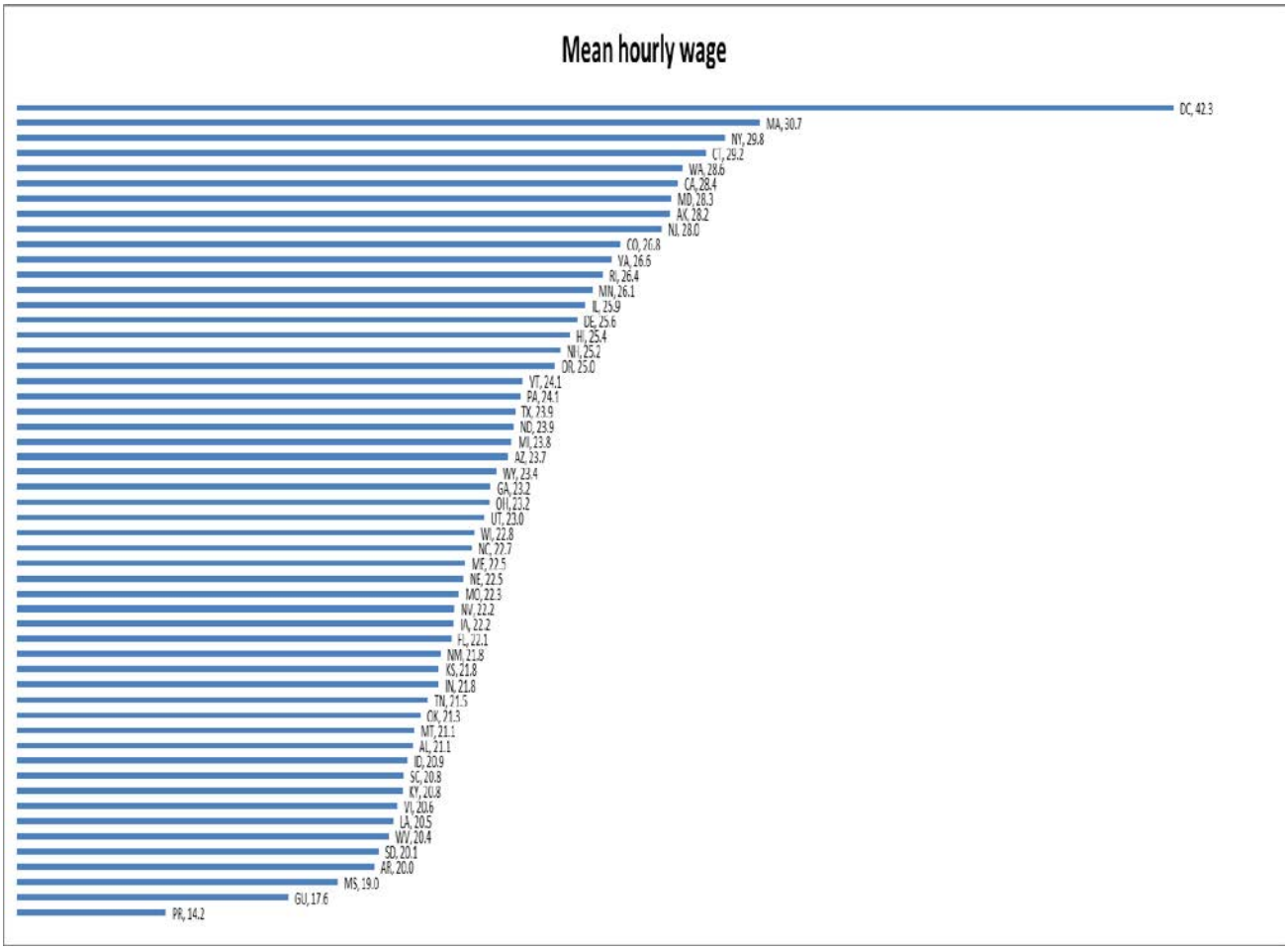
The Massachusetts Health & Hospital Association (MHA), on behalf of our member hospitals and health systems, appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) hospital inpatient prospective payment system (IPPS) proposed rule for fiscal year (FY) 2020.

Area Wage Index Proposals

Modifications to Wage Index Values for Low-Wage and High-Wage Hospitals

CMS proposes to "increase the wage index for hospitals with a wage index value below the 25th percentile wage index" by a value "equal to half the difference between the otherwise applicable final wage index value for a year for that hospital and 25th percentile wage index value for that year across all hospitals." Because of the budget neutrality requirement, this increase would be paid for by "the creation of a wage ceiling." The "ceiling" would be applied by "decreasing the wage index values for high wage index hospitals [those in the top quartile] by a uniform factor of the distance between the hospital's otherwise applicable wage index and the 75th percentile wage index for a fiscal year across all hospitals." The "uniform factor" would be 4.3% in FY2020. CMS proposes that this policy be effective for at least four years, beginning in FY2020.

CMS notes that there are "growing disparities" in the wage index system and claims that the agency's proposal is a mechanism to address these disparities, but we urge the agency to continue to recognize that there are true "disparities" in the cost of labor and cost of living between different parts of the country. According to the May 2018 Occupational Employment Statistics Survey conducted by the Bureau of Labor Statistics, Department of Labor, the mean hourly wage for "all occupations" varies from $14.16 in Puerto Rico to $ 42.27 in Washington D.C.



Since the area wage index is intended to recognize these differences in resource use across types and location of hospitals, *there will and should always be wage index "disparities."* In a quest to smooth out so-called "disparities", we urge CMS not to lose sight of the fact that it should continue to accurately and adequately account for these resource differences in its payment systems, as is clearly required by the statute that created the inpatient prospective payment system.

MHA is strongly opposed to CMS' proposal to increase the wage indices for hospitals with wage indices below the 25th quartile by reducing the wage indices for hospitals above the 75th percentile.

MHA appreciates CMS' recognition of the fact that certain hospitals, including rural hospitals, may be in financial distress, facing potential closure and in need of relief. However, we note that there are "high-wage index hospitals," including several in Massachusetts, that have negative margins and are struggling financially, and we, therefore, question whether a direct link can be made between the Medicare wage index and hospitals' financial performance. CMS has, to our knowledge, conducted no analysis or study establishing this link and, therefore, we question whether the Medicare wage index is the appropriate mechanism to attempt to improve the financial performance of low-wage index hospitals. CMS also has not proposed to "tie" the proposed increase in the wage index of low-wage hospitals to a demonstrated increase in employee compensation at those hospitals, or even expressed a commitment to do so.

For years, the labor share for hospitals with wage indices below 1.000 has been set at a lower level than the labor share for those above 1.000, which serves to cushion the impact of the wage adjustment for the former. Has CMS conducted an analysis of this policy's impact? If not, would it not be advisable for the agency to analyze the effect that the "lower labor share" policy has had on these hospitals and to also analyze and compare other options for its stated purpose of providing relief to low-wage hospitals? These options could include further lowering the labor share for these hospitals, or creating a dedicated "pool of funds" that low-wage hospitals could draw upon provided they commit to and demonstrate a corresponding increase in the wages of their employees.

Instead, CMS proposes to artificially shrink the wage index distribution nationwide by "compressing the quartiles" – that is, increasing the wage index values for some hospitals by cutting payments to a subset of other hospitals. This would artificially increase the wage index for providers with low-wage indices, potentially even to a level much higher than the prevailing wage levels in their market area; and this increase would be achieved by removing very significant Medicare funding from high-wage index hospitals whose wage index reflects the higher cost labor market conditions in the areas where they are located. It would effectively mean that a struggling community hospital in a high-wage area would have to sustain deep Medicare payment cuts in order to subsidize arbitrary – and quite possibly unfounded – positive payment adjustments for hospitals in low-wage states.

CMS has included no plans to even track whether artificially increasing the wage index of low-wage hospitals will deliver the desired results; nor has the agency proposed any specific requirements for the low-wage hospitals to demonstrate such results. With little evidence of similar policies having worked in the past, CMS' proposal appears to be a poorly researched, expensive redistributive experiment.

We also note that CMS cites as authority for this change "section 1886(d)(3)(E) of the Act (which gives the Secretary broad authority to adjust for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level, and requires those adjustments to be budget neutral), and under our exceptions and adjustments authority under section 1886(d)(5)(I) of the Act." We disagree with this interpretation. While MHA and our member hospitals are still reviewing this change with legal counsel, we believe the proposal would not withstand legal challenge. We urge the agency to not adopt it in the final rule.

Should CMS nevertheless decide to proceed with its policy to artificially increase the wage indices of hospitals below the 25th percentile, the agency should fund this temporary relief through a national budget neutrality adjustment, as is the norm, and not by its current proposal to decrease reimbursement to a selected subset of hospitals that have genuinely higher labor costs. "Selective" budget neutrality, as proposed by CMS, whereby a small subset of hospitals bears the entire burden of budget neutrality for a given CMS policy change is unprecedented, and it violates both the statutory purpose of the wage index and CMS' own long-standing policy of ensuring budget neutrality by spreading the cost of payment adjustments across all hospitals equally.

Modifications to Rural Floor Calculation

CMS proposes to no longer include wage index data from urban hospitals that reclassify as rural when calculating each state's rural floor. If finalized, CMS would include only geographically rural hospitals – not those that reclassify as rural – when calculating the rural floor for a state.

Specifically, CMS proposes to "remove urban to rural reclassifications under section 401 of the Balanced Budget Refinement Act from the calculation of the rural floor. ***MHA is strongly opposed.***

Our reading of the statute is that it is unambiguous that CMS must treat reclassified hospitals as being located in "rural areas" and that it must calculate the "rural floor" using the wage data of all hospitals located in "rural areas in the State". It does not draw any distinction between the "rural areas" used to calculate the rural floor under section 4410(a) of the Balanced Budget Act of 1997 and the "rural areas" that reclassified hospitals are to be treated as located in under section 1886(d)(8)(E) of the Social Security Act; both the rural floor and the reclassification provisions use the same definition for "rural area". In a nutshell, the term "rural areas" has the same meaning across the entire prospective payment system; Congress has intended that the term have *the same definition applicable to the rural floor and section 401 without modifications or exceptions.*

Since the rural floor prohibits urban hospitals not located in a "rural area" from receiving a wage index lower than the wage index of such "rural areas," and reclassified hospitals are to be treated as if they are located in a "rural area," then it follows that urban hospitals cannot have a lower wage index than hospitals located in "rural areas," including reclassified hospitals. Excluding reclassified hospitals from the rural floor is plainly inconsistent with the statutory language, irrespective of CMS' policy preference or the agency's read of legislative history.

While MHA and our member hospitals are still reviewing this change with legal counsel, we believe the proposal would not withstand legal challenge. We urge the agency to not adopt it in the final rule.

Cap on Decrease in Wage Index from FY 2019 to FY 2020

CMS also proposes to cap any decrease in a hospital's final wage index in FY 2020 compared to its final wage index in FY 2019 at 5%. This provision would ensure that a hospital's FY 2020 final wage index value would be no less than 95% of its final wage index for FY 2019.

As with any other changes in CMS' payment policy, particularly those changes that can cause very significant and harmful declines in hospitals' reimbursement from year to year, we believe that a glide path is essential. With respect to the two proposed area wage index policy changes for 2020 (that is, modifications to wage index values for low-wage and high-wage hospitals and modifications to the rural floor calculation), a glide path is *even more essential* because of the drastic nature of payment reductions implicated and the likelihood that CMS lacks the legal authority to move forward with either of these aforementioned proposals. As a result, hospitals must be protected from the dire financial consequences of these proposals until the sector has had enough time to evaluate and determine the legal basis and validity of the two proposals.

In the absence of the 95% stop-loss provision, our member hospitals would face a sudden and dramatic decline in reimbursement that may place them in a precarious financial position. ***We therefore urge CMS to ensure that a hospital's FY 2020 final wage index value would be no less than 95% of its final wage index for FY 2019.***

Disproportionate Share Hospital (DSH) Payment Methodology

As CMS begins relying solely on S-10 for calculating Uncompensated Care (UC) costs, the accuracy and equity of S-10 data will be increasingly important to ensure consistency across the field.

MHA supports using the FY2015 Cost Report to determine hospital Uncompensated Care.

For FY 2020, CMS proposes to use one year of data—from audited FY 2015 Worksheet S-10 data—and eliminate the low-income insured days proxy. In the rule, CMS states that averaging multiple years of data could "dilute" the effect of the audit and potentially lead to "a less smooth result." While MHA remains concerned with using the Worksheet S-10 as the basis of distributing Medicare DSH funding as described below, we support the CMS proposal to use the FY2015 cost report in the current construct for determining the relative share of hospital uncompensated care nationwide. As data integrity has been a significant concern with this methodology, ***we believe it is important that CMS use the audited FY2015 data***. We also note that CMS provided hospitals the opportunity to resubmit Worksheet S-10 filings during FY2015 to address any needed corrections and we understand many hospitals took advantage of this.

CMS should provide clear guidelines on its audit protocols and minimize burdens related to the audit.

This past year, select hospitals across the country underwent an audit of Worksheet S-10 data. MHA supports the audit of the S-10 data to ensure the data are sufficiently accurate and consistent. A change in even one hospital's reported UC costs will alter its Factor 3 and, in turn, affect all other hospitals' Factor 3 values.

We recognize that this first year of S-10 audits was new for hospitals as well as CMS and auditors. While hospitals were able to meet the request of auditors, we note that the timeline expected of hospitals was not reasonable. Hospitals were initially given only two weeks to respond to requests for detailed information related to charges and payments for *all* patient services reported as uncompensated care and bad debt. This request resulted in voluminous amounts of information to be queried and submitted to auditors. Some of the requested data elements were also unnecessary for this type of audit, including patient social security numbers, dates of birth, gender, names, and admission and discharge dates. Supplying this level of detail can be especially challenging for bad debt cases. Hospital administrative burden is a sizable and a major obstacle in reducing hospital cost growth; significant staff time is devoted to the many operational and financial duties related to Medicare and all other payers. ***MHA respectfully requests future S-10 audits be done with more advance notice to allow hospitals to appropriately respond. We also ask that CMS revisit the scope of the audit to reduce the burden placed on hospitals.***

The audit protocols have also not yet been made public. MHA is interested in how different Medicare Administrative Contractors (MACs) were instructed and interpreted CMS instructions. It is important CMS share its protocols and findings with stakeholders to ensure MACs and subcontractors consistently apply audit protocols across hospitals nationwide.

CMS should include medical education costs when using the S-10 to determine UC costs.

The cost-to-charge ratio in line 1 currently does not include medical education costs. MHA respectfully recommends including these costs, which can be derived from Worksheet B, column 24, line 118. Graduate medical education should be recognized as it is a significant cost incurred by teaching hospitals that care for all patients, including low-income Medicare, Medicaid, and uninsured patients.

CMS should issue clarifying guidance related to patient out-of-pocket expenses.

MHA respectfully requests CMS clarify the instructions on line 29 regarding non-Medicare bad debt for insured patients. For accuracy purposes, CMS should allow hospitals to include coinsurance and

deductibles on the S-10 without multiplying these amounts by the cost-to-charge ratio (CCR). CMS cost report instructions and guidance, as revised last year, dictate hospitals do not have to multiply non-reimbursed *Medicare* bad debt by the CCR, because coinsurance and deductibles are actual amounts expected from the patient (as opposed to charges, which are not the actual amounts a patient is expected to pay). However, the CMS September 2017 transmittal states that hospitals still should multiply their *non-Medicare* bad debt by the CCR. The different treatment of non-reimbursed Medicare bad debt and non-Medicare bad debt is inconsistent and we believe there is no justification to reduce co-insurance amounts for one payer and not the other. Hospitals should be permitted to list unpaid co-insurance and deductible amounts as bad debt in their entirety, and CMS should not reduce those amounts by the CCR. Making this change would be consistent with the way CMS treats charity care amounts for insured patients.

CMS should include a stop-loss protection for hospitals and revisit the use of S-10 data.

MHA remains very concerned with the implementation of the new policy of distributing Medicare DSH funding from a standard well-defined and uniform data point (a hospital day) to one that is non-standard and defined uniquely by every hospital across the country (hospital charity care and bad debt). The amount of uncompensated care reported by a hospital is dependent on how that hospital individually defines and writes-off care provided to patients who are unable to pay and who meet certain financial criteria as defined by the hospital. MHA believes that hospitals across the country are reporting uncompensated care inconsistently given that charity care and accounting practices vary between hospitals. Even with the audits, our opinion is the S-10 data on hospital uncompensated care remains questionable and there should be caution in using this data for distributing billions of DSH dollars. Alternative methods should be considered in the future in consultation with hospitals. In the meantime, we respectfully request CMS implement a stop-loss policy to protect hospitals that lose more than 10 percent in DSH payments in any given year given the transition to this new data set. This protection will also help hospitals with decreasing uncompensated care payments adjust to their new payment levels.

Hospital Readmissions Reduction Program (HRRP)

MHA urges CMS to monitor and respond to ongoing concerns about the HRRP that threaten the fairness and sustainability of the program. First and foremost, the agency should engage with the field to evolve its approach to socioeconomic adjustment. Any program directed at reducing readmissions must target preventable readmissions and include an appropriate risk-adjustment methodology.

In FY 2019, CMS took an important step toward improving the HRRP's fairness by implementing the congressionally mandated socioeconomic adjustment approach that places hospitals into dual-eligible peer groups to calculate their penalties. But Congress intended for this adjustment to be a starting point and granted CMS the ability to update the approach beginning in FY 2021. It is essential that CMS's socioeconomic adjustment approach keeps up with the evolving measurement science around accounting for social risk factors. The methodology currently used to calculate the readmission measures does not incorporate risk adjustment for sociodemographic status, language, post-discharge support structure, or other factors that reflect the challenges involved in caring for disadvantaged populations. Race, homelessness, cultural and linguistic barriers, low literacy, and other socioeconomic factors can skew results on certain quality measures, such as those for readmissions. It is well known that patients who lack reliable support systems after discharge are more likely to be readmitted. We encourage CMS to consider various risk adjustment and stratification approaches, both in measure development and in risk-adjustment methodology.

MHA also urges CMS to work with a range of stakeholders – including hospitals, patients and health services researchers – to assess whether the HRRP has had a negative impact on hospital mortality rates. Emerging research suggests that the HRRP's strong incentive to reduce readmissions could be associated with higher mortality rates. Given the divergent nature of the evidence around the link of readmissions to mortality, it is critical for CMS to examine this issue further to assess what changes to measure design and/or program implementation might be needed to the measures to avoid such an association.

MHA is concerned that at least some of the measures in the program may be approaching "topped out" status, and we urge CMS to consider phasing out these measures***. MHA strongly supports CMS's proposal to add the same measure removal criteria to the HRRP that are used in other CMS hospital quality measurement programs.*** However, we also encourage CMS to strengthen these criteria by considering the use of numerical criteria to determine "topped out" performance. We believe CMS should enhance the objectivity and consistency of the "topped out" measure criterion by adopting the same numerical criteria that it uses in the hospital inpatient quality reporting (IQR) and value-based purchasing (VBP) programs. When a measure is topped out, performance is so high and unvarying across providers that meaningful distinctions are no longer possible. But, in the absence of numerical criteria, this important concept could be applied somewhat subjectively.

Using measures with limited variation means that hospitals can experience significantly different readmission penalties based on only small differences in performance. Moreover, retaining "topped out" measures in the HRRP could detract from quality improvement efforts because hospitals would spend resources attempting to improve performance on the current HRRP measures, rather than on other measures with greater opportunity to improve. Given the significant implications of the program, CMS should begin to assess whether other clinical conditions with more variation would be more appropriate to assess in the program. It can use this assessment to develop suitable program measures and seek endorsement of them by the National Quality Forum.

Look Back Period for Dual-Eligible Status.

MHA supports CMS's proposal to implement a one-month "look back" period to assess patients' dual-eligible status. CMS identifies dual-eligible patients using the state Medicare Modernization Act (MMA) file, which states submit to CMS monthly. Currently, a patient counts as "dual-eligible" if they had full-benefit status in both Medicare and Medicaid for the month the beneficiary was discharged from the hospital. However, CMS identified two circumstances in which its current definition of dual-eligible may lead to the underreporting of the number of dual-eligible beneficiaries – 1) the dual-eligible status is not recorded in the month a patient dies; and 2) a patient's status changes from dual-eligible to non-dual eligible during the month of death. Thus, CMS would modify the definition of "dual-eligible" who die in the month of discharge by identifying their dual-eligible status using the previous month's MMA file.

Sub-Regulatory Process for Non-Substantive Changes.

In prior rulemaking, CMS adopted a sub-regulatory approach for minor updates to the HRRP's measure specifications. It now proposes to use a sub-regulatory approach for updates to the calculation of HRRP payment adjustment factors, such as minor changes to data sourcing. ***MHA urges CMS to add a safeguard to its final policy in which it explicitly states that any programmatic changes that impact hospital performance must go through notice and comment rulemaking.*** MHA strongly believes that all of CMS's programs – especially those like the HRRP that have a significant impact on provider payment – should operate on a transparent, "no surprises" basis. Any changes that have an impact to individual

hospital performance, and/or to the program performance distribution, should be communicated in advance of their implementation.

HAC Reduction Program

We urge CMS to take a number of steps to improve the program's fairness. This includes the following:

- Phase out the Patient Safety Indicator (PSI) measure. PSIs lack the accuracy, validity and usefulness to be suitable for any public reporting and pay-for-performance use.

- Require that measures newly added to the HAC Reduction Program be publicly reported for at least a year before tying the measure to hospital payment. MHA believes public reporting is an essential step before tying a measure to payment that allows for all stakeholders to ensure there are no adverse unintended consequences of reporting a measure.

- Removing the measure overlap between the VBP and HAC Programs. We believe that using the same measures in programs with different scoring methodologies and data reporting periods simply creates confusion for hospitals, rather than a stronger incentive to improve performance.

Chimeric Antigen Receptor (CAR) T-Cell Therapy

MHA supports CMS's decision to continue assigning CAR T-cell therapy to MS-DRG 016 for FY 2020 and allowing these services to be eligible for NTAP and outlier payments. However, MHA remains concerned that Medicare reimbursement is not keeping pace with the costs of new therapies and treatments. CMS is proposing to continue the NTAP for CAR T-cell therapy for FY 2020. MHA supports this proposal, and also CMS's proposal to increase the NTAP limit to $242,450. However, even with the increase in the NTAP, the cost of the CAR T-cell therapy alone far exceeds Medicare's reimbursement, leaving hospitals that provide CAR T-cell therapy facing losses in the hundreds of thousands of dollars in the inpatient services that are required for this care. Such losses are unsustainable for hospitals and pose a threat to patient access for this treatment as well as other care in general.

If CMS chooses to create a new MS-DRG for CAR T-cell therapy cases, it is imperative that the Agency ensure adequate reimbursement that reflects the true costs of the treatment and its associated complications. Furthermore, if new CAR T-cell therapies currently in the pipeline do not qualify for the NTAP, then hospitals will face an even greater reimbursement shortfall in the coming years as these emerging therapies change the modalities used for cancer care. Failing to adequately reimburse providers for the cost of the care will threaten beneficiary access to CAR T-cell therapy. CMS has yet to address the driver behind the high cost of these treatments – manufacturers' pricing of new therapies. In addition, these therapies often require intensive care unit stays or other intensive inpatient therapy that requires multiple medical specialists providing integrated care. Hospitals that provide CAR T-cell therapy must ensure that they have all related services available for immediate use, even if they are only required for a subset of patients.

MHA continues to urge CMS to consider carving out these very costly new technologies from the MS-DRG and paying for them on a pass-through basis. Doing so would help ensure not only the integrity of the budget-neutral inpatient PPS, but also, more importantly, beneficiary access to these life-saving technologies. This is especially necessary given that both new and existing therapies are expected to be approved for additional indications. The current payment systems – of any payer, not just Medicare –

were not built to sustain access to therapies with costs of these magnitudes. As technology continues to advance, therapies such as these will become more and more prevalent.

In the rule, CMS proposes to continue its NTAP approval for both CAR T products, KYMRIAH™ and YESCARTA™, in FY 2020. We strongly support this proposal. In addition, we appreciate the proposed change in NTAP rate from 50% to 65% for new technologies, including CAR T. However, while this proposal is a step in the right direction, we continue to believe that a higher NTAP for CAR T is needed to ensure beneficiary access to these therapies. Thus, we continue to urge CMS to make NTAPs for CAR T at a rate of 100%. We urge CMS to consider extending NTAP approval for CAR T beyond FY 2020 if a new MS-DRG – or pass-through payment – is not developed at the time CAR T "newness" expires. As they were envisioned, NTAPs offer a temporary respite from the high costs associated with providing access to new technologies, until the time at which sufficient data are available to incorporate those technologies into the Medicare DRG system.

While CMS does not propose to create a new MS-DRG for CAR T for FY 2020, MHA recommends that CMS continue exploring this approach as additional data is collected. A new MS-DRG would potentially allow for much more accurate reimbursement of these treatments since the weight of this new MS-DRG would directly reflect the extremely intensive resources involved since they would not be averaged together with much less resource-intensive treatments. We recommend that CMS exclude clinical trial CAR T cases in the development of a new MS-DRG, given the substantial differences in costs between trial and non-trial cases. We also recommend that CMS refrain from trimming the CAR T data when determining the weight for a potential DRG.

CMS questions whether IME and DSH should be applicable if a new MS-DRG is created after FY 2020. According to the Agency, "these percentage add-on payments could arguably result in unreasonably high additional payments for CAR T-Cell therapy cases unrelated to any significant empirical way to the costs of the hospital in providing care." However, as Congress made clear when it added IME to when the IPPS was originally developed in 1983, its purpose is to be "a proxy to account for a number of factors which may legitimately increase costs in teaching hospitals." Even as new therapies and DRGs emerge, these costs continue to exist and must be paid on every MS-DRG. MHA strongly opposes any exclusions or reductions to these or other MS-DRG add-on payment adjustments and believes that the Agency does not have the authority to impose these changes. Reducing or eliminating the IME add-on payment will harm teaching hospitals' ability to provide these critical health care services as well as the other services that the IME and DSH payments support. ***MHA supports the application of indirect graduate medical education (IME) and Medicare DSH adjustments to the full DRG payment under a new MS-DRG for CAR T in recognition of the purpose and usage of the two programs.***

Reductions in MS-DRG Payments

In the proposed rule, CMS proposes a number of significant reductions to the relative weights of certain MS-DRGs, which could potentially limit access to these necessary services for Medicare beneficiaries. For example, CMS's calculations of the relative weight for MS-DRG 215 ("Other Heart Assist Implant") would lead to a 25 percent reduction in FY 2019, which comes on the heels of a 20 percent reduction in FY 2018 and would result in a cumulative decline of more than 40 percent over two years. The impact of a decrease of this magnitude over two years would have a significant negative impact on hospitals that care for critically ill cardiovascular patients who require the implantation of a heart pump in the operating room or cardiac catheterization laboratory after heart attacks or decompensating heart failure. MHA urges the agency to phase in substantial fluctuations in payment rates in order to promote predictability and

reliability for the hospital field. We appreciated that the agency limited the payment decrease for MS-DRG 215 for FY 2018, and we urge CMS to again consider such an approach in this situation or when the relative weight for any MS-DRG is drastically reduced in a given year, particularly when it follows a significant decline in the previous year.

Inpatient Quality Reporting Program

Required Reporting of Hybrid Hospital-Wide, All-Condition Readmission Measure.

The claims-based hospital-wide readmissions measure is an inaccurate representation of quality. Since claims data are not clinically validated, the data do not accurately represent the quality of care provided at a hospital. As such, ***we support CMS's proposal to remove the claims-based hospital-wide readmission measure and encourage CMS to remove this claims-only measure sooner than the FY 2026 payment determination,*** as proposed.

CMS has stated its intent to consider the use of core clinical data elements from hospital EHRs in conjunction with other sources of data, such as administrative claims, to calculate "hybrid" outcome measures. One such hybrid measure has been developed: a hospital-wide 30-day readmission measure. CMS proposes a two-year voluntary reporting period before requiring hospitals to report this hybrid measure for the FY 2026 payment determination. CMS should undertake thorough public testing and vetting for accuracy and usability before making any data publicly available and ensure accuracy and completeness of the data submitted. *We urge CMS to allow additional time before this measure becomes mandatory in the IQR Program.*

Proposed opioid-related eCQMs.

The proposed safe use of opioids eCQM seeks to assess nationwide rates of concurrent prescribing of opioids and benzodiazepines at the hospital level. The hospital harm-opioid-related adverse events eCQM is designed to assess the administration of naloxone as an indicator of harm to reduce adverse events associated with the administration of opioids in the hospital setting. We encourage further development and field testing of these measures, with input from stakeholders, to ensure the information collected accurately reflects quality of care. Before introducing more measures, it is necessary to balance the usefulness of information reported through EHRs with the challenges of extracting such data and the accuracy of the information captured. *We urge CMS to examine whether these eCQMs are a viable option for all hospitals and to vet new eCQMs across EHR vendors and hospitals before considering the measures for program inclusion.*

Potential Future Quality Measures.

Hospital harm-severe hypoglycemia and hospital harm-pressure injury eCQMs: The first measure assesses the rate at which severe hypoglycemia events caused by hospital administration of medications occur in the acute-care hospital setting. The second measure assesses the rate at which new hospital-acquired pressure injuries occur during an acute-care hospitalization. NQF review of these measures is scheduled for June 2019. CMS should not include these measures in public reporting programs until they are fully tested and receive NQF endorsement.

It is not entirely clear from available information whether hypoglycemia is an issue of sufficient scale across all hospitals to warrant inclusion in a national reporting program. At a time when CMS is rightly

focused on "Meaningful Measures," we urge CMS to ensure the measure is not focused on an overly narrow issue.

Hospital harm – Pressure injury eCQM: This measure relies heavily on documentation of injuries within the first 24 hours of arrival at the hospital, which is a major challenge. Documentation of injuries of the various stages during this very busy period is extremely difficult, and it is unclear whether this measure relies upon physician documentation alone or whether nurse notes also would contribute to identification of these injuries. Performance on quality measures should be influenced only by the care provided, not on the variable documentation of that care. Also, the measure does not adequately adjust for the various risk factors associated with pressure injuries, including proportion of ICU patients, frailty, nutrition, ECMO patients and multiple injuries. Teaching hospitals and safety net hospitals care for patients more susceptible to pressure injuries, so their performance on this measure would likely be comparably low through no fault of the providers.

Cesarean birth (PC-02) eCQM: MHA is concerned that the measure lacks risk adjustment, which could lead to inappropriate performance comparisons between referral centers for high-risk deliveries and other hospitals. The measure also fails to exclude patients with eclampsia or pre-eclampsia, for whom CB may be indicated. As specified, the measure likely is detecting differences in patient populations rather than differences in quality performance. Further, we question the feasibility of implementing PC-02 as an eCQM. The data elements necessary to calculate the measure are not available in a structured format within current EHRs, and it is unclear whether they would capture data as accurately as through chart-abstraction. Because of these logistical and conceptual issues, as well as the overall importance of measures regarding maternal health, MHA recommends that CMS seek other ways to surveil quality of care on this issue.

Thank you for your attention to these important issues. Please contact MHA's Senior Director of Healthcare Finance and Research, Anu Puri, at (781) 262-6049 if you have any questions about our comments.

Sincerely,

Steve Walsh
President & CEO
Massachusetts Health & Hospital Association